

**REMARKS/ARGUMENTS**

Applicant gratefully acknowledges the courtesy shown by Examiner Fronda in the telephonic interview with the undersigned of Darby & Darby on June 9, 2005. During the interview the withdrawal of claims 9, 10 and 13; the enablement rejections under 35 U.S.C. § 112, first paragraph; the written description rejections under 35 U.S.C. § 112, first paragraph; and the obviousness rejections under 35 U.S.C. § 103(a) were discussed. Pursuant to the interview, Applicants include below arguments in support of their positions on these issues.

Claims 1-10, 13, 18 and 22-33 have been withdrawn. Claims 11, 12 and 21 have been canceled without prejudice. Claims 9, 15 and 20 have been amended. Claims 9 and 15 have been amended to recite that the Ozz protein “shares about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2.” Support for this amendment can be found in the specification at page 7, lines 21-23. Claim 15 has also been amended to recite that full-length Ozz protein comprises about 285 amino acids. Support for this amendment can be found in the specification at page 7, lines 1-3. Claim 20 has been amended for the purpose of added clarity.

**Withdrawal of Claims 9, 10 and 13**

Claims 9, 10 and 13 have been withdrawn because the Examiner contends that they recite non-elected subject matter. According to the Examiner, SEQ ID NO:4 is patentably distinct from SEQ ID NO:2, which is the “elected amino acid sequence” for murine Ozz protein. The Applicant respectfully traverses this withdrawal. In the Response to Restriction Requirement dated December 23, 2003, claims 9-17 and 19-21 and SEQ ID NO:1 were elected with traverse. These claims are directed to a murine Ozz nucleic acid. Claims 9, 10 and 13 are directed to a nucleic acid,

not an amino acid sequence, and the recitation of SEQ ID NO:4 is an acceptable limitation on the claimed nucleic acids.

In accordance with the discussion during the June 9, 2005 interview, claim 9 has been amended to recite: “shares about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2” instead of SEQ ID NO:4. As disclosed in the specification, “human [SEQ ID NO:4] and murine [SEQ ID NO:2] Ozz share 90% sequence identity, and 92% sequence similarity. Thus, the term Ozz encompasses polypeptides having about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2 or 4” (specification, page 7, lines 21-23).

Accordingly, claims 9, 10 and 13 should not be withdrawn.

#### **Claim Objections**

Claim 14 has been rejected because the Examiner contends that it depends from a non-elected claim (i.e., claim 9). Applicant respectfully traverses this objection. In accordance with the argument above, claim 9 is drawn to the elected subject matter. Thus, this objection should be removed.

#### **Rejection under 35 U.S.C. §112, First Paragraph, Enablement**

The Examiner has rejected claim 20 under 35 U.S.C. § 112, 1<sup>st</sup> paragraph for lack of enablement. According to the Examiner, “no guidance or prediction” is provided regarding “the specific hybridization conditions that would effectively screen out any hybridization to any region of the PPCA exon Ia” (Office Action mailed March 14, 2005, page 3). Thus, the Examiner contends that it would require undue experimentation to determine the hybridization conditions that would not result in the claimed nucleic acid hybridizing to any region of the PPCA exon Ia. This rejection is respectfully traversed.

Claim 20 is directed to an isolated nucleic acid. One of ordinary skill in the art could easily sequence a nucleic acid that hybridizes under the recited conditions to the nucleotide sequence of SEQ ID NO:1, and compare it to the sequence of the PPCA exon Ia (as noted in the Response filed October 28, 2004, the sequence of PPCA exon Ia was known). A nucleic acid sequence that does not correspond to the sequence of this exon is covered under the claim. All that is required of the skilled artisan is to recognize the PPCA exon 1 and exclude it. No determination of hybridization conditions is required. No undue experimentation is required.

**Rejection under 35 U.S.C. §112, First Paragraph, Written Description**

The Examiner has rejected claims 15-17 and 19 under 35 U.S.C. § 112, first paragraph, alleging that there is an insufficient written description of the claimed genus of nucleic acids encoding a fragment of Ozz protein. According to the Examiner, the claims “are directed to any vector comprising any nucleic acid of any nucleotide sequence and structure encoding any Ozz protein or fragment of any amino acid sequence and structure” (Office Action, page 4).

Claim 16 recites that the nucleic acid encodes full length Ozz protein. Thus, claim 16 satisfies the written description requirement because it is directed to a nucleic acid that encodes a specific protein, not “any Ozz protein or fragment.”

Claims 15-17 and 19, as amended, are directed to a well-described genus of nucleic acids encoding a fragment of an Ozz protein.

Contrary to the Office Action, the Federal Circuit held that a genus is sufficiently described if an adequate number of representative species is described, *or* (not “and”) the common characteristics of the genus are described. *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569 (Fed. Cir. 1997). The common characteristics of the genus of nucleic acids in claims 15

and 16 (directed to a vector), claim 17 (directed to a host cell) and claim 19 (directed to a method for producing Ozz protein) are adequately described by the structural limitations that the nucleic acid encodes a fragment of Ozz protein wherein full-length Ozz protein has the recited sequence identity or sequence similarity with SEQ ID NO:2 and comprises about 285 amino acids, and the functional limitation that the encoded fragment has the ability to bind  $\beta$ -catenin, myosin, c-Nap or Alix.

Accordingly, this rejection should be withdrawn.

**Rejection under 35 U.S.C. §103(a)**

Claims 15-17 and 19 have been rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,643,758 (“Guan”) in view of Prinos et al., *Teratology*. 1998;57(2):108 (“Prinos”).

According to the Examiner, Guan discloses an expression vector containing an *E.coli* maltose binding protein, host cells transformed with this vector, and isolation of the maltose binding protein produced by the host cells. The Examiner acknowledges that Guan does not disclose a vector comprising a nucleic acid encoding Ozz protein or a fragment thereof. The Examiner contends that Prinos discloses cDNA for a mouse homolog of the *Drosophila* neuralized gene and, “in the absence of facts to the contrary [this homolog] is expected to be capable of binding beta-catenin, myosin, c-Nap, or Alix” (Office Action, page 5). The Examiner has not provided any support for this assertion. According to the Examiner, the instant specification discloses that Ozz has homology to *Drosophila* neuralized gene.

This rejection is respectfully traversed. Neither Guan nor Prinos discloses or suggests a nucleic acid encoding a protein, which shares about 90% sequence identity or about 92% sequence similarity with SEQ ID NO:2 as recited in the amended claims. Further, neither Guan nor Prinos

discloses or suggests a protein comprising about 285 amino acids. Guan discloses a completely unrelated 370 amino acid protein (i.e., maltose binding protein) (Guan, col. 6, lines 30-31), and Prinos discloses a 574 amino acid protein (Prinos, line 15). Accordingly, the amended claims are not obvious in view of Guan and Prinos.

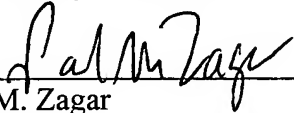
**Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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